

ADELMAN *et al.*  
Application No.: 09/254,590  
Page 11

80-90% identity) over a core sequence of approximately 300 amino acids. Furthermore, this family of channels share functional characteristics, such as pharmacological properties (apamin sensitivity) and small conductance properties.

***Status of the claims***

New claims 56-99 have been added. These claims are directed to nucleic acids encoding potassium channel monomers of the SK gene family. These claims add no new matter. Support for these claims can be found, e.g., in claims 1-10, 19, 26-28, 30, 36-42, and 44-46 as originally filed. Support can also be found in the specification on page 20, lines 28-29, page 24, lines 12-13, page 28, lines 21-31, and page 73, lines 29-31.

***Response to restriction requirement***

In response to the restriction requirement dated March 19, 2001, Applicants elect to prosecute Group II, claims 1-4, 6, 8-10, 19, 26-28, 30, 36-42, and 44-46, drawn to isolated nucleic acids encoding hSK2 and methods of use in hybridization assays. This Group corresponds to new claims 56-66 and 78 to 88.

Applicants first note that claims 5 and 7 were not placed in any group. However, as these claims were drawn to nucleic acids, Applicants would expect that they would be included in the correct group (Groups I-VII). Furthermore, the Examiner failed to indicate the class and subclass corresponding to each group.

The foregoing election is made with traverse, as claims 1-4, 6, 8-10, 19, 26-28, 30, 36-42, and 44-46 were placed in Groups I-VI. As such, on its face this rejection is improper and should be withdrawn. By placing claims 1-4, 6, 8-10, 19, 26-28, 30, 36-42, and 44-46 in six separate groups, the Examiner has improperly attempted both to reject these claims for misjoinder, and to reject the claims on the basis that they allegedly represent independent and distinct inventions. Furthermore, examining the claims together would not place an undue examination burden on the Examiner.

ADELMAN *et al.*  
Application No.: 09/254,590  
Page 12

*A. An Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions*

By restricting a single claim and placing it in more than one group, the Examiner is alleging that the single claim represents multiple "patentably distinct" inventions. As such, this type of restriction requirement is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber, Soder and Boksay*, 198 USPQ 328, 331 (C.C.P.A. 1978). *See also In re Haas*, 179 USPQ 623, 624-625 (C.C.P.A. 1973) (*In re Haas I*); and *In re Haas*, 198 USPQ 334, 334-337 (C.C.P.A. 1978) (*In re Haas II*). *See also* MPEP § 803.02.

Moreover, it has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See In re Weber*, 198 USPQ at 328. The courts have definitively ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See id.*; *In re Haas I*, 179 USPQ at 623; and *In re Haas II*, 198 USPQ at 334. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-no

ADELMAN *et al.*  
Application No.: 09/254,590  
Page 13

matter how broad, which means no matter how many independently patentable inventions may fall within it. *In re Weber*, 198 USPQ at 334.

As described above, the claims are directed to a highly conserved family of genes, the SK family. This genus of nucleic acids is claimed on the basis of common structural and functional features. Although the individual species of the genus may also be separately patentable, the genus as a whole represents a single invention. Therefore, rejecting claims 1-4, 6, 8-10, 19, 26-28, 30, 36-42, and 44-4, respectively, for misjoinder is therefore clearly improper. Applicants thus respectfully request that the Examiner withdraw the improper restriction requirement with respect to Groups I-VI.

*B. Examining the claims of Groups I-VI together does not place an undue examination burden on the Examiner*

Furthermore, restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. MPEP § 803.01. Applicants respectfully submit that examining the claims of Groups I-VI together (nucleic acids encoding SK potassium channel monomers) would not place an undue burden on the Examiner.

In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner must show one of the following, as set forth in MPEP § 808.02:

- (1) *Separate classification thereof:*  
This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(2) *A separate status in the art when they are classifiable together:*  
Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(3) *A different field of search:*  
Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.  
Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

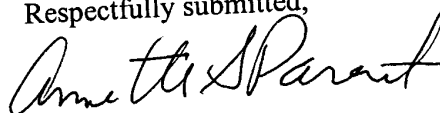
In the present case, the Examiner has not provided the class and subclass of the Groups. However, the present claims relate to a genus of SK nucleic acids, which are claimed by common structural and functional features. Applicants submit that searching Groups I-VI, corresponding to new claims new claims 56-99, places no undue examination burden on the Examiner. In particular, the claims corresponding to individual SK genes (SK1, claims 67-77; SK2, claims 78-88; and SK3, claims 89-99) should be examined together, without restricting the claims into individual orthologs of a gene. Applicants therefore respectfully request that the restriction requirement with respect to Groups I-VI, be withdrawn.

ADELMAN *et al.*  
Application No.: 09/254,590  
Page 15

CONCLUSION

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Annette S. Parent  
Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: (415) 576-0200  
Fax: (415) 576-0300  
SF 1214964 v1